UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,946	01/05/2006	Jithan Aukunuru	OP/4-32592A	2284

1095 7590 02/26/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
BASQUILL, SEAN M	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,946	AUKUNURU ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2009*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-53* is/are pending in the application.

4a) Of the above claim(s) *44 and 50-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-43 and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21 Jan 2005; 10 Nov 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Claims 28-43 and 45-49 in the reply filed on 6 January 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-27 having been cancelled, and Claims 44 and 50-53 having been withdrawn as directed to nonelected inventions, Claims 28-43 and 45-49 are presented for examination.

Priority

2. Applicant's claim for the benefit of the prior-filed provisional application 60/397,865 and PCT application PCT/EP03/08005 under 35 U.S.C. 119(e) and 365(c) is acknowledged.

Information Disclosure Statement

3. The information disclosure statement filed 21 January 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein which has been lined through has not been considered.

Specification

4. The abstract of the disclosure is objected to because the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The use of the trademarks CREMOPHOR EL, NIKKOL HCO-60, BRADOSOL, GERMAL II, PURITE, POLYQUART, DEQUEST, CAVAMAX, CAVASOL have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

6. Claim 49 is objected to because of the following informalities: the description of the concentration of the staurosporine derivative appears to be missing a unit of measurement, such as "0.1-4 mg," or "0.1-4%." Appropriate correction is required.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28-43 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See*, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed

invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "staurosporine derivatives" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. *See Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful staurosporine derivatives generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of species including hydrocarbyl or acyl radicals at pages 7-10, and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 28-43 and 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 28 recites the phrase "semisolid ophthalmic composition" without providing a means for determining what state of matter would qualify as semisolid.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003) (holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the values recited by the instant claim 28 are incomplete insofar as they do not

specify the frame of reference used to measure them, e.g., by specifying a particular viscosity or range of viscosities which would qualify the composition as "semisolid."

9. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 34 recites the phrase "parts by weight" without specifying what weight the claim refers to.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003) (holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the values recited by the instant claim 34 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., "the total weight of the composition," or "percentage of the composition."

10. Claims 38 and 39 recite the limitation "wherein 'n' is a number..." in Claim 35. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 contains the trademark/trade name CREMOPHOR EL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyethoxylated castor oil and, accordingly, the identification/description is indefinite.

12. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" is indefinite because it is unclear how far one can deviate from the parent compound without the "derivative" being so far removed therefrom as to be a completely different compound. See the related rejection in the "Written Description" section *supra.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 28-33, 35, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,579,901 (hereinafter "Chen") as evidenced by U.S. Patent 3,134,718 (hereinafter "Nobile").

Chen discloses eye ointments comprising in one embodiment tacrolimus, anhydrous lanolin, liquid paraffin, vaseline, and polyoxyethylated castor oil (C.3, L.50-55) and in another embodiment tacrolimus, anhydrous lanolin, liquid paraffin, vaseline, and HCO60. (C.5, L.20-50). One embodiment, example 4, contains HCO60 in a concentration of 2.29% by weight of the composition. (C.5, L.20-30).

Nobile indicates that anhydrous lanolin and wool fat are synonymous. (C.20, L.60, 71).

14. Claims 28-33, 42, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,107,343 (hereinafter "Sallmann").

Sallmann discloses an eye ointment containing phenylethyl alcohol (5%) as a preservative, cetylstearyl alcohol (2.2%), liquid paraffin (2.07%), white petrolatum (4.62%) and wool fat (14.15%). (C.9, L.10-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,107,343 (hereinafter "Sallmann"), as applied to claims 28-33, 42, and 47 above.

Sallmann discloses an eye ointment containing phenylethyl alcohol (5%) as a preservative, cetylstearyl alcohol (2.2%), liquid paraffin (2.07%), white petrolatum (4.62%) and wool fat (14.15%) described above. Sallmann also indicates that topical ophthalmic compositions can include solubilizers such as polyethylene glycols and polyethoxylated castor oils such as Cremophor EL in concentrations of between 0.1-5000 times that of the active agent. (C.4, L.52-67). Specifically, PEG 400 is listed as one of the polyethylene glycols usable in the instant invention. (C.5, L.45-46).

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251,

1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of solubilizers and fillers, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed solubilizers and fillers from within Sallmann, to arrive at compositions "yielding no more than one would expect from such an arrangement."

16. Claims 43, 45, 46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sallmann as applied to claims 28-33, 35-42, and 47 above, and further in view of U.S. Patent 5,093,330 (hereinafter "Caravatti").

Sallmann discloses an eye ointment containing phenylethyl alcohol (0.5%) as a preservative, cetylstearyl alcohol (2.2%), liquid paraffin (2.07%), white petrolatum (4.62%) and wool fat (14.15%) described above. Sallmann also indicates that topical ophthalmic compositions can include solubilizers such as polyethylene glycols and polyethoxylated castor oils such as Cremophor EL. Specifically, PEG 400 is listed as one of the polyethylene glycols usable in the instant invention. The particular eye ointments described by Sallmann are for the delivery of drugs to treat ocular inflammatory disorders and all ophthalmological disorders involving inflammatory processes. (C.3, L.27-30).

Sallmann does not specify the inclusion of staurosporine derivatives, particularly midostaurin, in compositions for the treatment of inflammatory ocular disorders.

Caravatti describes the use of staurosporine derivatives, particularly midostaurin (Example 18, C.28, L.45-57; C.2, L.40 – C.3, L.5; C.3, L.57), in compositions for the treatment of diseases modulated by protein kinase C, including use as an immunomodulator or antiinflammatory. (C.2, L.18-50).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have used antiinflammatory staurosporine derivatives, particularly midostaurin described by Caravatti in the topical ophthalmic composition described by Sallmann. One having ordinary skill in the art at the time of the instant invention would have been motivated to use midostaurin in the composition of Sallmann because the art recognized the antiinflammatory properties of midostaurin, as well as the use of the composition of Sallmann in delivering ocular antiinflammatory agents. The combination of the two simply represents the combination of elements known by the art as suitable for their intended purpose.

17. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sallmann as modified by Caravatti, as applied to Claims 28-33, 35-43, and 45-48 above above.

Sallman as modified by Caravatti provides a composition comprising midostaurin, phenylethyl alcohol (0.5%) as a preservative, cetylstearyl alcohol (2.2%), liquid paraffin (2.07%), white petrolatum (4.62%) and wool fat (14.15%), and solubilizers such as polyethylene glycols and polyethoxylated castor oils such as Cremophor EL in the concentrations as described above.

Neither Sallmann nor Caravatti describes the precise concentrations of all ingredients as taught in instant Claim 49, however, the combination of Sallmann and Caravatti does disclose the general conditions of the concentrations of each element of the composition as claimed.

Where the general conditions of a claim are known via the prior art, it is not inventive to discover optimum or workable concentration ranges by the routine experimentation of one having ordinary skill in the art, absent evidence presented indicating the claimed range is critical. MPEP § 2144.05(II)(A).

18. Claims 36-39 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen as applied to Claims 28-33, 35, and 42 above, and further in view of U.S. Patent 4,524,075 (Hereinafter "Oduro"), and Shulin Ding, *Recent Developments in Ophthalmic Drug Delivery*, 1 PSTT 328 (November 1998) (Hereinafter "Ding").

Chen describes ophthalmic compositions containing tacrolimus, anhydrous lanolin, yellow vaseline, and polyoxyethylated castor oil or tacrolimus, anhydrous lanolin, liquid

paraffin, yellow vaseline, and HCO60, as described above. Chen additionally indicates additives such as surfactants and bacterial suppressants are incorporated into ophthalmic compositions. (C.3, L.1-9).

Chen does not describe ophthalmic compositions comprising a polyethylene glycol.

Oduro describes the use of polyethylene glycols such as PEG 400 for the formation of eye ointments or eye drops of a desired consistency. (C.2, L.20-42). Oduro indicates that the chosen PEG should be present in a concentration of at least 1% by weight of the composition. (C.2, L.57-60). Oduro additionally indicates that appropriate additional conventional additives such as preservatives may be incorporated into compositions for ocular administration, along with compatible conventional carriers like ointment bases. (C.2, L.43-47).

Ding teaches that the use of viscosity enhancers are commonly used in topical ophthalmic pharmaceuticals to prolong residence time and improve bioavailability of the active agents. (Pg. 328-29).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to include a preservative and polyethylene glycol viscosity enhancer such as PEG 400 in the composition of Chen. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so in order to increase the viscosity of the ophthalmic composition and improve bioavailability of the active agent without increasing the concentration of active agent in the composition.

19. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen as applied to Claims 28-33, 35, 42, and 47 above, and further in view of U.S. Patent 6,015,797 (hereinafter "Camborde").

Chen describes ophthalmic compositions containing tacrolimus, anhydrous lanolin, vaseline, and polyoxyethylated castor oil or tacrolimus, anhydrous lanolin, liquid paraffin, vaseline, and HCO60, as described above.

Chen does not describe ophthalmic compositions comprising a polyethoxylated castor oil with the properties disclosed in instant Claims 40 and 41.

Camborde discloses the use of Cremophor El as the castor oil carrier of ophthalmic compositions for the delivery of therapeutic agents such as dextromethorphan (C.6, L.34-38), diazepam (C.7, L.7-14), and morphine sulfate (C.8, L.1-7).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have used Cremophor El as the castor oil of the composition of Chen. One having ordinary skill in the art would have been motivated to substitute Cremophor EL on the basis of their art-recognized equivalence as castor oil bases for ophthalmic compositions.

20. Claims 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen as applied to claims 28-33, 35, 40-42, and 47 above, and further in view of U.S. Patent 5,093,330 (hereinafter "Caravatti"), and U.S. Patent 6,114,320 (hereinafter "Aiello").

Chen describes ophthalmic compositions containing tacrolimus, anhydrous lanolin, vaseline, and polyoxyethylated castor oil or tacrolimus, anhydrous lanolin, liquid paraffin, vaseline, and HCO60, as described above.

Chen does not describe ophthalmic compositions comprising staurosporine derivatives such as midostaurin.

Caravatti describes the use of staurosporine derivatives, particularly midostaurin (Example 18, C.28, L.45-57; C.2, L.40 – C.3, L.5; C.3, L.57), in compositions for the treatment of diseases modulated by protein kinase C, including use as an immunomodulator or antiinflammatory. (C.2, L.18-50).

Aiello describes the use of protein kinase C inhibitors for the treatment of ocular vascular disorders.

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have used staurosporine derivatives such as midostaurin in a composition for the treatment of ocular disorders. One having ordinary skill in the art would have been motivated to combine a staurosporine derivatives such as midostaurin with the composition of Chen because Caravatti describes staurosporine derivatives such as midostaurin as protein kinase C inhibitors, and Aiello recognizes such inhibitors as effective in treating ocular disorders such as those treated by the tacrolimus used in the composition of Chen; the art recognizes the suitability of staurosporine derivatives such as midostaurin as effective treatments for ocular diseases like those described in Chen.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642